Remarks

Claims 35-59 are pending. Claims 35-42 are withdrawn. Claims 43, 46, and 51 have been amended. It is noted that the claims have been amended to resort to the claims previously presented in the Response to Office Action of July 6, 2007. This was done in response to the Notice of Non-Responsive Amendment of December 24, 2008, which alleged that the claims presented in the Response to Office Action of July 6, 2007 were constructively elected by original presentation. Applicants respectfully traverse the allegation that the newly amended claims found in the Response to Office Action of June 11, 2008 are not readable on the originally presented invention. However, in an effort to expedite prosecution, Applicants have resorted to the claims before they were amended in response to the Office Action of June 11, 2008. Applicants respectfully request reconsideration of the claims as currently presented.

Priority

The Office Action states that, "The preliminary amendment is drawn to a method of classifying a cancer as being correlated with expression of an erbB-3 gene. However, the preliminary amendment as filed contains subject matter not otherwise included in the specification and drawings of the application since neither the term 'classifying' nor the concept of classifying a cancer as being correlated with expression of an erbB-3 gene is found in the specification as originally filed." Applicants respectfully disagree. Specifically, the oldest priority document, now U.S. Patent 5,183,884, teaches the concept of the classification of cancer using erbB-3 in col. 2, lines 2-19; col. 2, lines 57-62; col. 8, lines 35-46; col. 10, line 66 to col. 11 line 10; col. 11, lines 11-16; and col. 15, line 6 to col. 16, line 22. Therefore, it is clearly

demonstrated that the concept of classifying a cancer is taught. Therefore, applicants respectfully request that the present claims be given priority to December 1, 1989.

Claim Rejections – 35 USC § 112, First Paragraph

Claims 43-46 and 51-59 were rejected under 35 U.S.C. § 112, first paragraph, for allegedly not containing a written description of the claimed invention. Applicants respectfully traverse this rejection. The Office Action alleges that the claims are drawn to a broad genus of erbB-3 genes of unknown structure and function Applicants respectfully disagree.

The courts have clearly established that the first paragraph of 35 U.S.C. § 112 includes, *inter alia*, two separate requirements: (1) an enablement requirement based on the statutory language that the application describe "the manner and process of making and using [the invention], in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same," and (2) a written description requirement based on the statutory language "[t]he specification shall contain a written description of the invention" (the third requirement of the first paragraph of 35 U.S.C. § 112, the "best mode" requirement, is not relevant here). The separate status of the make and use clause and the written description clause was at the heart of the recognition of the separate written description requirement. *See Vas-Cath v. Mahurkar*, 935 F.2d 1555, 1560-61 (Fed. Cir. 1991); *Enzo Biochem v. Gen-Probe*, 285 F.3d 1013, 1018, 1021 (Fed. Cir. 2002) (hereafter "*Enzo I*")).

The essential goal of this written description requirement is to clearly convey the information that an applicant has invented the subject matter which is claimed. *See In re Barker*, 559 F.2d 588, 592 n.4, 194 USPQ 470, 473 n.4 (CCPA 1977). Another objective is to put the public in possession of what the applicant claims as the invention. *See The Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1566; 43 USPQ2d 1398, 1404 (Fed. Cir. 1997) (hereafter, "*Lilly*").

Lilly is often cited to support a written description rejection of claims to genetic sequences, because it established that an adequate written description for genes requires more than the name of the gene and a statement of its function, it "requires a precise definition, such as by structure, formula, chemical name, or physical properties." *Lilly*, 119 F.3d at 1566; 43 USPQ2d at 1404. However, the courts have for the most part limited the holding in *Lilly* to the facts of that case. For example, the Federal Circuit rejected the idea that written description requires a disclosure of structure for DNA inventions. *See Enzo Biochem, Inc. v. Gen-Probe Inc.* (*Enzo II*), 323 F.3d 956 (Fed. Cir. 2002) (finding that deposit of DNA sequences satisfied written description for a claim to subsequences and variants of the sequences). In fact, the Federal Circuit appears to have further limited the relevance of *Lilly* to "new or unknown biological materials that ordinarily skilled artisans would easily miscomprehend." *Amgen v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1332 (Fed. Cir. 2003). Consistent with this, the Federal Circuit has stated that it does not require patentees to recite known DNA structures, i.e., does not require a re-description of what was already known. *Falko-Gunter Falkner v. Inglis*, 448 F.3d 1357 (Fed. Cir. 2006). erbB-3, and variants thereof, were known in the art at the time of the

invention, and one of skill in the art would have easily envisaged erbB-3 as presently described in the instant specification.

The Patent Office undertook a review of the written description caselaw in view of *Lilly* in order to establish guidelines for the examination of patent applications for compliance with the written description requirement of 35 U.S.C. § 112, first paragraph. *See Guidelines for Examination of Patent Applications Under 35 U.S.C. 112, ¶1 "Written Description" Requirement*, 66 Fed. Reg. 1,099 (Jan. 5, 2001) (hereafter, "*Written Description Guidelines*"). Far from requiring any absolute or *per se* requirement for adequate written description, the resulting *Written Description Guidelines* provide a case-specific and fact-dependant inquiry. This is consistent with caselaw, where compliance with the written description requirement is consistently referred to as a fact-dependent inquiry. *See, e.g., Vas-Cath v. Mahurkar*, 935 F.2d 1555 (Fed. Cir. 1991).

"Actual reduction to practice may be crucial in the relatively rare instances where the level of knowledge and level of skill are such that those of skill in the art cannot describe a composition structurally ... in such a way as to distinguish the composition with particularity from all others." *Written Description Guidelines,* Response to Comment 7, pg. 1101.
"If an adequate description is provided, it will suffice 'whether located among the original claims or in the descriptive part of the specification.'" *Written Description Guidelines,* Response to Comment 17, pg. 1102, citing *In re Gardner*, 480 F.2d 879, 880, 178 USPQ 149 (CCPA 1973). Applicants therefore respectfully request withdrawal of this rejection.

Claim Rejections – 35 USC § 102

Claims 43-46, 51, 52, 55, and 58 were rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Lemoine et al (Br J Cancer, December 1992, 66:1116-1121), as evidenced by Prigent et al (Oncogene, July 1992, 7:1273-1278). Applicants respectfully traverse this rejection. As pointed out above, the claims as amended have priority to U.S. Patent 5,183,884, which has a filing date of December 1, 1989. Therefore, the art of Lemoine from 1992 is not properly applied. Applicants therefore respectfully request withdrawal of this rejection.

Claims 43-45, 51-53, 55, 57, and 58 were rejected under 35 U.S.C. 102(b) as being allegedly being anticipated by Rajkumar et al (J of Pathology, 1993, 170:271-278), as evidenced by EP 0 444 961 A1, Plowman et al, published September 4, 1991. Applicants respectfully traverse this rejection. As pointed out above, the claims have priority to U.S. Patent 5,183,884, which has a filing date of December 1, 1989. Therefore, the art of Rajkumar et al. (1993) is not properly applied. Applicants therefore respectfully request withdrawal of this rejection.

Claim Rejections – 35 USC § 103

Claims 43-45, 51, 52, 55, and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prigent et al (Oncogene, July 1992, 7:1273-1278) in view of Lemoine et al II (Gut, October 1992, 33:1297-1300).

Applicants respectfully traverse this rejection. As pointed out above, the claims as amended have priority to U.S. Patent 5,183,884, which has a filing date of December 1, 1989. Therefore, the art of Prigent et al. (1992) is not properly applied. Applicants therefore respectfully request withdrawal of this rejection.

No fee is believed to be due; however, the Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.Respectfully submitted,

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